UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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FEDERAL TRADE COMMISSION, STATE OF NEW YORK, STATE OF CALIFORNIA, STATE OF OHIO, COMMONWEALTH OF PENNSYLVANIA, STATE OF ILLINOIS, STATE OF NORTH CAROLINA, and COMMONWEALTH OF VIRGINIA,

Plaintiffs,

v. 20 CV 706 (DLC)

MARTIN SHKRELI, et al.,

Defendants.

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New York, N.Y.
December 21, 2021
9:30 a.m.

Before:

HON. DENISE COTE,
District Judge

APPEARANCES

FEDERAL TRADE COMMISSION
BY: MARKUS H. MEIER
MARIN HANEBERG
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NEAL PERLMAN
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ANDREW J. RUDOWITZ
SARAH FEHM STEWART
SEAN McCONNELL
J. MANLY PARKS

(In open court; trial resumed)

THE COURT: So, counsel, I forgot to put on the record yesterday your use of time, but we communicated that to counsel after court ended. The plaintiffs have used 14 hours and two minutes, and the defendant has used 12 hours and 18 minutes.

Let's talk a little bit about where we stand. I understand that Dr. Jena is the last witness. Is that true?

MR. CASEY: Yes, your Honor, that's correct.

THE COURT: Yesterday, Ms. Kirby's affidavit was received that constitutes her direct testimony, but I take it, then, the plaintiffs are waiving their right to cross-examine Ms. Kirby?

MR. MEIER: Your Honor, I think we have an understanding -- Markus Meier, for the FTC, sorry — that we will put in, and I think we've put in, her deposition testimony. So one of the things we moved in was deposition testimony, and Ms. Kirby will not be appearing live, and, through agreement with the defendants, we used the deposition testimony instead.

THE COURT: Let me make sure.

(Pause)

THE COURT: So, counsel, this last weekend, I reviewed, I thought, all the deposition designations that were being offered by the parties. I did not understand at that time that Ms. Kirby's dep designations were being offered by

the parties because I thought she was going to be a witness. So I will now read the deposition designations for Ms. Kirby.

Is there anyone else who might fall in that category, where -- I've read Mr. Shkreli's designations. Anyone else?

MR. MEIER: Yes, your Honor. Markus Meier, for the FTC.

Also, Eve Costopoulos.

THE COURT: I read hers.

MR. MEIER: That would be it, as far as I understand.

MR. RUDOWITZ: Your Honor, this is AJ Rudowitz, on behalf of Mark Shkreli.

I believe that we will be offering today Danny Bailey and Amanda Lopez's deposition designations. I don't think that those fall into the same category as someone who is expected to testify, but now is not, but I just wanted to let your Honor know that we do intend to offer those today.

THE COURT: Bailey, I have read.

And which other one?

MR. RUDOWITZ: Amanda Lopez, your Honor.

THE COURT: Yes, I read that.

MR. MEIER: Your Honor --

THE COURT: Excuse me one second.

(Pause)

MR. MEIER: I wanted to add that plaintiffs will be admitting this morning, or seeking to admit, the deposition

testimony of Ron Tilles. The difference between Costopoulos and Kirby is they put in written directs, and we've counterdesignated depositions. Mr. Tilles is not a written direct, he's just another witness with a --

THE COURT: Yes, and I read his designations, also, this weekend.

MR. MEIER: Thank you.

THE COURT: So, what is my roadmap for my assignments is the document that defense counsel gave me at the beginning of the trial. So, thank you very much. It's been very useful to me.

Okay, good.

Let's get Dr. Jena back on the stand, and then I want to talk with counsel about how we organize ourselves for tomorrow with summations and other cleanup issues.

Dr. Jena, thank you for your patience. Please retake the stand.

THE WITNESS: Thank you. Good morning.

THE COURT: Good morning. I remind you, you are still under oath.

Cross-examination?

MR. MEIER: Your Honor, there are a couple of administrative matters, if we may, first?

THE COURT: Sure.

MR. MEIER: We have two things that the plaintiffs

would like to move in, and then defendants have two that they would like to move in.

This is all by agreement, as I understand it. The first is: Government Exhibit 9007.

THE COURT: Any objection to the receipt of GX 9007 and the exhibits listed therein?

MS. STEWART: Sarah Stewart, your Honor.

No objection, subject to your Honor's rulings. Thank you.

THE COURT: Received.

(Government's Exhibit 9007 and exhibits listed therein received in evidence)

MR. MEIER: The last one for the plaintiffs, your Honor, is Government Exhibit 9074. It is the deposition transcript excerpts of Ronald Tilles, T-i-l-l-e-s, from Vyera.

THE COURT: Any objection to receipt of GX 9074?

MR. RUDOWITZ: RJ Rudowitz, your Honor.

No objection.

THE COURT: It's received.

(Government's Exhibit 9074 received in evidence)

THE COURT: I notice that there are some passages that are being withdrawn. I'm going to try to be hypervigilant about that as I finalize my opinion.

Thank you.

Anything from defense counsel?

MR. CASEY: Yes, your Honor. We have several exhibits to move in evidence at this point.

THE COURT: And you want to do that now, or do you wish to wait until your expert is off the stand?

MR. CASEY: Whatever the Court prefers.

THE COURT: Your call, counsel.

MR. CASEY: We'll do it now, your Honor.

THE COURT: Great.

MR. RUDOWITZ: First, your Honor, is Defendant's Exhibit DX 801. This is the deposition designation to the transcript of the deposition of Danny Bailey.

THE COURT: Any objection to the receipt of DX 801?

MR. MEIER: No objection, your Honor.

THE COURT: Received.

(Defendant's Exhibit 801 received in evidence)

MR. RUDOWITZ: Your Honor, next will be Defendant's Exhibit DX 802. These are the deposition designations to the transcript of the deposition of Amanda Lopez.

THE COURT: Any objection?

MR. MEIER: No objection, your Honor.

THE COURT: Received.

(Defendant's Exhibit 802 received in evidence)

MS. STEWART: Your Honor, Sarah Stewart.

The next exhibit that we have to offer is DX 903. It lists various other exhibits that the parties have agreed may

be admitted into evidence.

THE COURT: Any objection to the receipt of DX 903 and the exhibits listed therein?

MR. MEIER: No objection, your Honor.

THE COURT: Received.

(Defendant's Exhibit 903 and exhibits listed therein received in evidence)

MS. STEWART: The last one, your Honor, is DX 904. It is another list of exhibits that the parties have conferred on and agreed may come into evidence.

THE COURT: Any objection to the receipt of DX 904 and the exhibits listed therein?

MR. MEIER: No objection, your Honor.

THE COURT: Received.

(Defendant's Exhibit 904 and exhibits listed therein received in evidence)

MR. CASEY: Your Honor, just one point of clarification. With respect to the Ron Tilles' deposition designations, just so the record is clear, we have no objections, subject to this Court's prior rulings.

THE COURT: Sure.

Counsel.

MR. MEIER: Thank you, your Honor. May it please the Court, Markus Meier, on behalf of the FTC.

Your Honor, it would be my intention to try to save

about eight minutes of the 58 minutes for possible redirect, and you may see some assistant come up and give me a note telling me that I'm running out of time.

ANUPAM JENA,

CROSS-EXAMINATION CONTINUED

BY MR. MEIER:

Q. Dr. Jena, I'd like to start where we left off yesterday afternoon — discussing your medical opinions in this case.

As we were just about to get started before the recess, I wanted to show you Government Exhibit 4088.

MR. MEIER: So if we could pull that up, please, Mr. Tuttle.

Q. While Mr. Tuttle is pulling that up, as part of your work in this case, you looked at the guidelines for the prevention and treatment of opportunistic infections, correct?

A. Yes, sir.

Q. And we discussed it during your deposition?

A. Yes, sir.

Q. And you do not cite the guidelines for the prevention and treatment of opportunistic infections by name in your trial testimony, but you do appear to discuss these guidelines, correct?

A. I believe that's correct.

Q. Let's start by looking at the cover page.

The cover page, do you see right under the headline,

there is a symbol of the Health and Human Services, and then it says, "Recommendations from The Centers for Disease Control and Prevention, The National Institutes of Health, and The HIV Medicine Association of The Infectious Diseases Society of America."

Do you see that?

A. Yes, sir.

Q. And the current director of the CDC is Dr. Rochelle Walensky?

A. Yes, sir.

Q. And Dr. Walensky was the chief of the Division of Infectious Diseases at Mass General Hospital, your hospital, correct?

A. Yes.

Q. And the current director of the NIH, National Institute of Allergy and Infectious Diseases, is Dr. Anthony Fauci?

A. Correct.

Q. Unfortunately, because of COVID, Drs. Walensky and Fauci have become household names for many of us, correct?

A. Agreed.

MR. MEIER: Let's turn to page A2, please, Bryce.

Q. So I'd like to bring your attention, in the middle of the first paragraph at the top, there's a sentence that begins with "the NIH and CDC."

Do you see that?

A. Yes, sir.
Q. It says, "The NIH and the CDC and the HIV Medicine Association of The Infectious Diseases Society of America now jointly cosponsor these guidelines, which have been published in peer-reviewed journals and/or the MMWR in 1997, 1999, and 2002. Since 2009, the guidelines have been managed as a living document on the Web with each chapter reviewed quarterly by the guidelines committee. Updates are published as often and as promptly as deemed appropriate by the guidelines committee."

Now, you're not a member of the guidelines committee, are you?
A. No, sir.
Q. Do you happen to know what the acronym MMWR stands for?
A. It's the Monthly Morbidity Weekly Review, I believe. It's published by the CDC and frequently would appear in the medical journal JAMA. That's the Journal of The American Medical Association.
Q. Is it correct that these guidelines are intended for clinicians and other healthcare providers, patients with HIV, and policymakers in the United States?
A. Yes, I think primarily healthcare professionals. I don't know the extent to which policymakers review these guidelines, but, certainly, healthcare providers.
Q. So just so you know, I was actually reading. I probably should have called your attention to it.

MR. MEIER: Let's go to the fourth paragraph down from the top, Mr. Tuttle.

Q. It says, "These guidelines are intended for clinicians, other healthcare providers, patients with HIV, and policymakers in the United States."

Do you see that?

A. Yes, sir.

Q. And as you said, the guidelines are intended for physicians like you, correct?

A. Correct.

Q. And they're designed for use by clinicians who may encounter certain infectious diseases only rarely?

A. Correct.

MR. MEIER: Still looking at page 2, moving down to that big paragraph there -- and I want to find the right sentence -- sort of in the middle, there's -- Mr. Tuttle, there's a place where it starts with "the working group's," and if you could just highlight that down to the word "indicate." The next couple lines, also, Mr. Tuttle, including the next sentence. Thank you, Mr. Tuttle.

Q. It says, "The working group's review in realtime the relevant literature published since the last review of the guidelines and, if indicated, propose revised recommendations, which are then presented to the coeditors and other working group leaders. The coeditors and working group leaders have a

teleconference quarterly to determine changes in each section that are indicated."

Do you see that?

A. Yes, sir.

Q. And you're not a coeditor, correct?

A. No, sir.

Q. And you're not a working group leader, correct?

A. No, sir.

Q. And the guidelines, as this would indicate, are constantly being updated to reflect the latest medical findings from the research; is that correct?

A. That's correct.

Q. And the guidelines have been updated throughout the time you've been a physician?

A. That's correct.

MR. MEIER: So if we could go to page 4 now, which is -- I'm sorry, page A4. That's 0035 of the document. I'm sorry, 005, excuse me.

Q. Do you see where there's a headline up near the top on how to use the information in these guidelines?

A. Yes, sir.

MR. MEIER: And then there's ten points, and then there's a paragraph that starts with "recommendations," so if we could just pull that up.

Q. And it says, "Recommendations are rated according to the

criteria in the table below and accompanied, as needed, by explanatory text that reviews the evidence and the working group's assessment. In this system, the letters A, B, or C signify the strength of the recommendation for or against a preventative or therapeutic measure, and the Roman numerals I, II, or III indicate the quality of the evidence supporting the recommendation."

Do you see that?

A. Yes, sir.

Q. So let's take a look at the table directly below that. This is essentially an explanation of the rating system used throughout the guidelines, correct?

A. Correct.

Q. And it consists of two elements, a strength of recommendation and the quality of evidence for the recommendation.

Do you see that?

A. Yes.

Q. So if I understand this correctly, AI would be the highest rated prevention and treatment recommendation and CIII would be the lowest?

A. Correct.

Q. So you'd agree that this rating system is fairly easy to understand and to use, correct?

A. I think so.

Q. So even people like us lawyers, who didn't go to medical school, could understand this, correct?
A. I think so.
Q. Okay. Thank you.
MR. MEIER: So let's turn to the section about Toxoplasma gondii encephalitis. And that would be AA-1.
Q. Looking at the very top, do you see, it says, "Last Updated July 25, 2017; Last Reviewed June 26, 2019"?
A. Yes.
Q. And then under the heading "Treating Disease," which is on page AA-3 -- I just want to focus on treating the disease -- it says, "The initial therapy of choice for TE" -- that would be Toxoplasma encephalitis, correct?
A. Correct.
Q. That is Toxoplasma in the brain?
A. That's correct.
Q. So it says, "The initial therapy of choice for TE consists of the combination of pyrimethamine plus sulfadiazine plus leucovorin," and then it says "AI," right?
A. Yes.
Q. And that's the highest rating that the guidelines give?
A. Correct.
MR. MEIER: And if we could go to page AA-9 under the heading "Recommendations for Preventing and Treating Toxoplasma Gondii." Sorry, Mr. Tuttle, I'm moving a little fast.

Q. Here's a chart that's part of a guidelines that then marches through the different ways to treat different manifestations of Toxoplasma, correct?
A. Correct.
Q. It says, "The preferred regimen, AI, is pyrimethamine 200 milligrams."
You see that?
A. Yes.
Q. And then there's a note.
You see where the note is?
A. Yes.
Q. It says, "If pyrimethamine is unavailable or there is a delay in obtaining it, TMP-SMX should be used in place of pyrimethamine sulfadiazine," and that gets a BI, correct?
A. That's correct. And I think it refers to the part of A3, which is the very bottom of A3, which refers to the comparative effectiveness evidence.
Q. So what the joint committees and organizations that have put together the guidelines and brought to bear the most recent understanding of the medical literature and updating it as necessary, they determined that pyrimethamine is an AI and TMP-SMX is a BI, correct?
A. That's correct, yes, sir.
Q. And the last one, it talks about atovaquone, and it says, "Atovaquone should be administered until therapeutic doses of

TMP-SMX are achieved," and that gets a CIII, correct?
A. Correct.
Q. So that's the least strong medical evidence and the least strong recommendation, correct?
A. Yes, sir.
MR. MEIER: Thank you, Mr. Tuttle. You can take this exhibit down now.
Q. Let's move to your opinions as an economic expert in this case. Okay?
A. Sure.
Q. Are you with me?
A. Yes, sir.
Q. Please turn to page 6 of your trial testimony.
Do you have it up there with you?
A. I do.
Q. I'm going to focus on Exhibit D.1.
Do you see that?
A. Yes, sir.
Q. And D.1 has a title "Quantity and Price of Daraprim Q1 2006 Through Q2 2015," correct?
A. Yes, sir.
Q. And Q1 would stand for the first quarter of 2006, i.e., January to March, correct?
A. Yes, sir.
Q. And Q2 would be the second quarter of 2015, which would be

April to June?

A. Yes, sir.

Q. All right.

So in paragraph 26 of your trial testimony -- that's right before the charts -- you write, "Daraprim received FDA approval in January of 1953 and was marketed worldwide by GlaxoSmithKline (hereinafter GSK) and its affiliated predecessors until 2010. As seen in Exhibit D.1, data reported by IQVIA, based on sales to wholesalers and other distributors, show that by 2010, the price charged per Daraprim tablet was approximately one dollar," correct?

A. Yes, sir.

Q. And going back to the chart on page 6, we can see that graphically by the blue line that's very flat running from 2006 to about the fourth -- roughly, the fourth quarter of 2010.

Do you see that?

A. Yes, sir.

Q. That's the price line, correct?

A. That's correct.

Q. That blue line?

And then the orange line, that's the line for tablets?

A. Correct.

Q. Measured in increments of 100,000, correct?

A. Yes, sir.

Q. So if we're reading this correctly, where you start the

chart in the first quarter of 2006, GSK was selling about 450,000 tablets a year -- I'm sorry, a quarter at the time at a price of a dollar a pill?

A. Correct.

Q. And that orangish line shows a steady decline, correct?

A. That's correct.

Q. And that steady decline indicates that the sales of Daraprim tablets was declining at a fairly constant rate over the period of your Exhibit D.1, correct?

A. Correct.

Q. And your Exhibit D.1 ends at the second quarter of 2015, correct?

A. Correct.

Q. And that's just before Vyera acquired the U.S. rights to Daraprim, correct?

A. Yes, sir.

THE COURT: Counsel, is it true that the correct way to read this chart is - could you inquire — 450,000 tablets per quarter?

MR. MEIER: I think you're right, your Honor. I think it's probably per year at that moment.

BY MR. MEIER:

Q. But, actually, Dr. Jena, how is the correct way to read that?

A. This would be by quarter. So if you look at the table of

notes it's priced at, it's quarterly gross sales by quarterly units, so I believe this would be per quarter. I'm not entirely sure. I'd have to look at the underlying data.

BY MR. MEIER:

Q. But what it's showing is it fluctuates -- there's fluctuation from quarter to quarter, but over time, the trend line is markedly going down, correct?

A. That's correct.

Q. So that by the second quarter of 2015, it looks like about 200,000 tablets, right, before Vyera acquires Daraprim?

A. That's correct.

And, just to clarify, I believe these are quarterly units.

Q. Okay. Can you just explain that real quickly, so we all understand what you mean by that?

A. Yes, sir. Units sold per quarter, so tablets sold per quarter.

Q. Okay. Thank you.

Now, the graph doesn't tell us anything about physician or patient switching away from Daraprim and using other drugs to treat toxoplasmosis, correct?

A. No, it does not.

Q. Instead, the downward trend in Daraprim sales reflect the increasing success that the medical community has had in diagnosing, preventing, and treating HIV, correct?

A. That's certainly part of it, but, from this graph, I couldn't conclude whether that's the only component or whether there's also changes over time in use of other drugs versus pyrimethamine, but I would expect that the primary component is what you just described.

Q. And nothing in your chart -- nothing in this graph tells us anything about switching to other drugs that might be used to treat toxoplasmosis, correct?

A. Correct.

Q. So your graph shows that even during the time GSK was charging a dollar a pill for Daraprim, the quantity of Daraprim sold declined from about 450,000 tablets to about 350,000 tablets per quarter, correct?

A. Yes, sir.

Q. That's about a 22 percent decline in quantity sold?

A. I think that's correct.

Q. And then it shows, your graph shows, that Daraprim price started going up from about a dollar a pill around the third quarter of 2010?

A. Yes, sir.

Q. And at some point, it goes all the way up to about $12, slightly under $12, a pill, correct?

A. Yes, sir.

Q. That's over about a five-year period, maybe four-and-a-half, five years?

A. Correct.
Q. And that's about an 1100 percent price increase?
A. I'll take your representation for that price increase, but the absolute increase is correct, from about $6 to about $12.
Q. So during the same time that Daraprim experienced a 1100 percent price increase, there was only about a 22 percent decline in quantity sold, correct?
A. Correct.
Q. And in Exhibit D.1 of your trial testimony, you use Daraprim pricing data from IQVIA, correct?
A. Correct.
Q. And this data, in this particular chart from IQVIA, doesn't include all rebates to payers and other types of discounts that Vyera might have offered or GSK might have offered or any other company that owned Daraprim might have offered?
A. Correct.
Q. You, nonetheless, found the IQVIA data sufficiently reliable to use as part of your trial testimony, correct?
A. Yes. Just to describe the overall trends in quantities sold and prices not inclusive of rebates.
Q. Thank you.

So let's turn to page 7, paragraph 29, of your trial testimony.

Are you with me?
A. Yes, sir.

Q. And this paragraph says, "On August 7, 2015, Impax sold its U.S. rights to market and distribute Daraprim to Vyera (known as Turing at the time). On August 11, 2015, Vyera increased the list price of Daraprim from approximately $17.60 per tablet to $750 per tablet."

Do you see that?

A. Yes, sir.

Q. So when Vyera raised its price of Daraprim to 750 in 2015, after that — I'm going to ask you about the next few years — Vyera's Daraprim sales were profitable in 2016, correct?

A. Correct.

Q. And they were profitable in 2017, correct?

A. Correct.

Q. And they were profitable in 2018, correct?

A. Correct.

Q. And they were profitable in 2019, correct?

A. Yes, sir.

Q. And Vyera's Daraprim sales were profitable in 2020?

A. Correct.

Q. In fact, Vyera's Daraprim sales have been profitable ever since the acquisition, correct?

A. Yes, sir.

Q. So Vyera didn't lose so many Daraprim sales so as to make the price increase to $750 per tablet unprofitable, correct?

A. That is correct. It lost, I think, something like

67 percent of its units sold, the quantity, but with that price increase, it remained profitable, as you just described.

Q. So Vyera didn't lose so many Daraprim sales so as to make the price increase to $750 per tablet unprofitable, correct?

A. Correct.

Q. Let's turn to page 29 of your trial testimony and look at Exhibit D.5. Page 29, Exhibit D.5.

Are you with me?

A. Yes, sir.

Q. Exhibit D.5 has a heading "Quantity of Daraprim Tablets Sold Q1 2006 To Q4 2020."

Do you see that?

A. Yes, sir.

Q. And, again, it shows some of the same trend line as DX 1, but it adds additional time periods after the second quarter of 2015, correct?

A. Yes, sir.

Q. What it shows, as I look at it — at least as I interpret it, but you can correct me — from the time Vyera acquired Daraprim in the third quarter of 2015 to the time of generic Daraprim entry in Q1 2020, Daraprim's sales remained relatively flat despite the 4,000 percent price increase, correct?

A. I think that's correct, but maybe I can just qualify it, if you're open to it, but I defer to you.

Q. We'll let your attorneys get up and qualify something if it

needs to be qualified.

A. Sure.

Q. This can be seen graphically by the yellow highlighter that Mr. Tuttle put on there, the sales are relatively flat from the period after Vyera has increased the price by 4,000 percent, correct?

A. Correct, the sales are relatively flat after the price increase, but, of course, prior to that, there's a large reduction in quantity, but after that, they remain relatively flat.

Q. Yes, thank you. So you got the explanation in after all.

Looking at Exhibit D.5, your Daraprim sales line changes from a dotted orangish line to a solid orangish line in the third quarter of 2015.

Do you see that?

A. Yes, sir.

Q. And according to the note and sources below, where you explain where the information came from, you switched from using IQVIA sales data for Daraprim to using Vyera sales data, correct?

A. Yes, sir.

Q. That's because you no longer found the IQVIA sales data for Daraprim sufficiently reliable after Vyera acquired Daraprim?

A. Yes, sir.

Q. In fact, also, you can see, between the second and third

quarter of 2015, you actually see an increase in the sales quantity for Vyera.

Do you see that?

MR. MEIER: Bryce, can you circle that area there, or highlight it. Thank you.

Q. Do you see that?

A. I do see that. I don't know that I'd call that an increase, given the fluctuation that we observed, but, visually, I do see that uptick.

Q. Yes, that's what it shows. It shows, visually, that there's a discernible increase in Daraprim sales when you first start using Vyera sales data instead of the IQVIA data, correct?

A. Again, visually, there's an uptick, but I wouldn't draw anything from that besides to say that, visually, I observe that.

Q. Yes, so that's all we've got to work with here, Dr. Jena. You didn't include any other things in your report that would explain this, so we're sort of stuck with what we see visually.

In fact, isn't this an indication that the IQVIA data was underreporting Daraprim sales?

A. I don't know if it's correct. I don't have a particular opinion on that.

Q. Well, you started using Vyera's data, didn't you, because the IQVIA data was no longer reliable because of Vyera's

data-blocking policy?

A. That is true.

Q. Now, generic drugs --

MR. MEIER: You can take that down, Mr. Tuttle.

Q. Generic drugs are medications that are created to be the same as an existing approved brand drug in dosage form, in safety, in strength, in route of administration, in quality, and in performance characteristics, correct?

A. Yes, sir.

Q. And that's actually a direct quote out of your written testimony.

You would agree that generic Daraprim is branded Daraprim's closest therapeutic substitute?

A. Yes, sir.

Q. Would you also agree that Daraprim is branded -- I'm sorry, generic Daraprim is branded Daraprim's closest economic substitute?

A. I would agree.

Q. That's basically because they're the same drug?

A. Yes, sir.

Q. Just different price?

A. Correct.

MR. MEIER: Mr. Tuttle, would you please put Government Exhibit 1093 on the screen.

And while Mr. Tuttle is doing that, your Honor, I'll

just point out for the record that Government Exhibit 1093 was admitted as part of a broader Government Exhibit 9013.

BY MR. MEIER:

Q. I'd like to show you what's been marked as Government Exhibit 1093, and just ask you to take a quick look at the email at the bottom from an Andrea Weddle to a number of people at turing.com.

I showed you this letter -- I'm sorry, this email at your deposition.

Do you have a recollection of that?

A. I do, and thanks for the correction.

Q. In the email from Ms. Weddle to the executives at Turing, it says, "I am sending the attached letter on behalf of the president of the Infectious Diseases Society of America, Stephen Calderwood, M.D., and the chair of the HIV Medicine Association, Adora Adimora, M.D., MPH to urge Turing Pharmaceuticals to immediately develop a rational and fair drug pricing strategy for the recently acquired drug pyrimethamine."

Do you see that?

A. Yes, sir.

Q. The next sentence says, "The price increase that took effect in the middle of August is negatively impacting patient care and challenging hospital systems across the country."

Do you see that?

A. Yes, sir.

Q. Now, you do not offer any opinion in your trial testimony on whether Vyera's Daraprim price increase in 2015 negatively impacted patient care and challenged hospital systems across the country, correct?

A. That's correct.

Q. Let's turn to page 2 of Government Exhibit 1083, which is the actual letter from the IDSA and HIVMA from September the 8th, 2015.

Do you see that?

A. Yes, sir.

MR. MEIER: If we could go down to the third paragraph of the letter, Mr. Tuttle.

Q. It says, "In mid-August, after Turing purchased pyrimethamine, the price of the medication increased by 5,000 percent in hospital pharmacies around the country with no justification for an increase of this magnitude for a medication approved by the U.S. Food and Drug Administration in 1953."

Do you see that?

A. Yes, sir.

Q. It says, "In addition, hospitals, including those with 340B pharmacies, also reported being unable to obtain the medication."

Do you see that?

A. Yes, sir.

Q. Now, you do not offer an opinion in your trial testimony that Vyera's Daraprim price increase was justified, correct?
A. That's correct.
Q. And you do not offer any opinion in your trial testimony contradicting the statement that after Vyera's Daraprim price increase, hospitals reported being unable to obtain Daraprim, correct?
A. That's correct. I don't assess that, one way or the other.
Q. Right.
MR. MEIER: We can take that letter down, Mr. Tuttle. Thank you.
Q. Turning to page 8 of your trial testimony, we're going to look at Table 1 on page 8. Table 1 on page 8 of your trial testimony has the heading "Summary of Generic Manufacturers' ANDAs."
Do you see that?
A. Yes, sir.
Q. And this is a chart, or a table, I should say, you put together in order to sort of give the dates when various generic manufacturers started working on ANDAs and the status, at least as of the time of your testimony, correct?
A. Yes, sir.
Q. If I'm reading this correctly, two of the companies, the first two companies, shows that they were starting to develop a generic version of Daraprim before Vyera even acquired Daraprim

and raised the prices 4,000 percent, correct?
A. Correct.
Q. This would have been in the period when the price was going up from about a dollar a pill to somewhere around 12 or 13 dollars a pill?
A. That's correct.
Q. So would it be fair to say that your Table 1 shows that at least two generics started working on generic Daraprim before Vyera acquired the rights?
A. I would say that's correct.
Q. And your table shows that at least two generic companies expected generic Daraprim entry would be profitable at a price somewhere around $12 a pill?
A. I don't have a particular opinion on that. I didn't analyze that specific question.
Q. Right.

But it would be irrational for them to have entered, sought to enter, when the price was $12 a pill, if they didn't think it was going to be profitable, correct?
A. I'd assume that's correct, but I don't have any insight into their business decisions.
Q. No, I understand you don't have insight into that.

But you do assume, as an industrial organization economist, that companies are profit-maximizing, correct?
A. I would agree with that.

Q. And that they don't purposely try to lose money, correct?
A. I would agree with that, but I don't know what they were forecasting for the price and quantity sold.
Q. Got it. Understood.
Have you ever had --
MR. MEIER: We can take that down, Mr. Tuttle.
Q. Have you ever had any communications of any kind with Martin Shkreli?
A. No, sir.
Q. You don't rely on anything from Martin Shkreli's deposition in forming any of your opinions in this case, correct?
A. Correct.
Q. You haven't even read Mr. Shkreli's deposition, correct?
A. Correct.
Q. You don't rely on anything from Mr. Shkreli's trial testimony in forming any of your opinions in this case, correct?
A. Correct, sir.
Q. You haven't even read Mr. Shkreli's written direct testimony in this case, correct?
A. No, sir, I've not.
Q. And you do not offer any opinions in your trial testimony on the role of Mr. Shkreli in this case, correct?
A. Correct.
Q. And you were not asked to define a relevant antitrust

product market in this case, correct?
A. Correct.
Q. And you were not asked to define a relevant antitrust geographic market, correct?
A. Correct.
Q. So you were not asked to offer any opinions challenging Professor Hemphill's opinion that the relevant geographic market in this case is the United States, correct?
A. Correct.
Q. And you don't define the relevant market for Daraprim in your trial testimony, correct?
A. That is correct.
Q. You don't calculate Daraprim's market share in your trial testimony, correct?
A. That is correct.
Q. You don't give an estimate of Daraprim's market share in your trial testimony, correct?
A. That's correct.
Q. And you were not asked to perform an excess profit calculation in this case, correct?
A. No, I was not. I was only asked to respond to Dr. Hemphill's calculations in his written testimony.
Q. And you don't offer any opinions in your trial testimony about barriers to entry into the market in which Daraprim competes, correct?

A. No, I do not.
Q. And you did not conduct an analysis of cross-price elasticity in this case, correct?
A. That's correct.
Q. So I'd like to ask you a hypothetical. Let's look, again, at page 8, Table 1, of your testimony. That's the one with the Summary of Generic Manufacturers' ANDAs.
Do you see that?
A. Yes, sir.
Q. So let's assume a world in which Vyera owns branded Daraprim and acquires each of the generic ANDAs in Table 1.
Are you with me?
A. Yes.
Q. Under these circumstances, would you expect Vyera to be able to profitably increase the price of Daraprim and its generics 5 to 10 percent?
A. I don't have a specific opinion on that. I couldn't tell you one way or the other.
Q. Well, let me ask you this: Assume a world in which Vyera owns branded Daraprim and pays Cerovene and Fera to exit the market for Daraprim.
Are you with me?
A. Yes.
Q. Do you have any opinion on whether Vyera would be able to profitably increase the price of Daraprim by 5 to 10 percent?

A. No, I do not.
Q. Let's turn to tab 3 of your trial testimony. Tab 3, it's in the back.
It's a little bit tricky to find, but it's the one with the big blue page that says, "Pharmaceutical Industry Antitrust Handbook, Second Edition."
Do you see that?
We've also got up it on the screen, if that helps.
A. Yes, now I see it. Thank you. I appreciate it.
Q. Is it fair to say given that you felt this was sufficiently important to attach to your trial testimony, that you relied on the ABA's Pharmaceutical Industry Antitrust Handbook in preparing your testimony?
A. Yes, sir.
Q. Indeed, you found the ABA's Pharmaceutical Industry Antitrust Handbook so important, that you actually included this excerpt as a tab to your trial testimony, correct?
A. Correct.
Q. If you look at the actual excerpt, if we go to page 236, where it has a heading "Competition from Generic Products," do you see that?
A. Yes, sir.
Q. And that's the excerpt that you chose to include as part of your report?
A. Yes, sir.

Q. And looking at the second sentence of the excerpt that starts with, "the entry of an AB rated generic," do you see that?

A. Yes, sir.

Q. It says, "The entry of an AB-rated generic equivalent to the branded drug typically has a powerful effect on the market price for the drug molecule."

Do you see that?

A. Yes, sir.

Q. Do you agree with that statement?

A. I would agree with that.

Q. It actually goes on to cite an FTC study, but we don't have time to go into that.

Let me go down to the part of the paragraph that starts with "the magnitude of this effect."

Do you see that?

A. Yes, sir.

Q. And it says, "The magnitude of this effect varies depending on how many generic manufacturers enter the market."

Do you see that?

A. I see that.

Q. Do you agree with that statement?

A. I would agree with that as a general point.

Q. So, generally speaking, the more generics that come in that are AB-rated to the brand, the lower the price goes for the

molecule?
A. That's correct. That's what the academic literature would suggest.
Q. And generic Daraprim is AB-rated to branded Daraprim, correct?
A. Yes, sir.
Q. So looking at the excerpt you chose to include, there is a heading that starts at the bottom that says, "Direct Evidence of Market Power."
Do you see that?
A. Yes, sir.
Q. But you didn't continue the excerpt at that point, did you?
A. No, sir.
Q. So you left off the section that discusses so-called direct evidence of market power, correct?
A. Well, I cite to the document. I don't have that explicitly in here, but I certainly cite to the document, but it is correct to say that the excerpt ends at page 236.
Q. Turning real quickly to your -- keep that page, if you can, hold onto the page --
A. Sure.
Q. -- but also turn back to paragraph 83 on page 18. It's a little bit of a juggling act. I'm going to ask you to keep your place.
A. Okay, I'm there.

Q. I'm sorry, I took you to the wrong place. I wanted to go to paragraph 133, excuse me, which is on page 34.

So, maintaining that juggling act, paragraph 133, page 34.

A. All right, I'm there. Thank you.

Q. And, here, you have some criticisms of Professor Hemphill, and you say, "Direct evidence of market power is typically unavailable, particularly in the pharmaceutical industry."

Do you see that?

A. Yes, sir.

Q. Now, you don't cite anything for that proposition, do you? You just state that essentially as an ipse dixit, correct?

A. I don't know what "ipse dixit" means, but I don't cite anything specific there to that statement.

Q. Okay. So it's just a statement you've made.

Now, let's turn back to the handbook, which you felt was sufficiently authoritative, that you included it in your report.

Do you know what the handbook has to say about direct evidence of market power?

A. My understanding is that it describes direct and indirect evidence, but it describes the role of direct evidence and market power.

Q. Do you know whether the handbook says anything similar to your statement that it is particularly in the pharmaceutical

industry that this type of data is unavailable?

A. Not specifically, but I'm happy to review something, if you would like to show it to me.

MR. MEIER: Your Honor, at this time, I would like to read into the record the section from the Pharmaceutical Antitrust Handbook that talks about direct evidence as a learned treatise.

"Although courts predominantly rely upon the relevant market analysis to determine market shares and the presence of market power, some courts evaluate market power by examining direct forms of proof, such as evidence of supercompetitive prices, barriers to entry, abnormally large profit margins, output restrictions, or subcompetitive quality or service."

Next paragraph: "The direct evidence approach has been advocated most strongly in cases alleging unlawful exclusion of generic competition."

Thank you, your Honor.

BY MR. MEIER:

Q. Let's turn to paragraph 22 on page 5.

A. I'm there.

Q. In paragraph 22, you talk about the experience at Mass General Hospital, correct?

A. Yes.

Q. You say, "As of January 2016, all inpatient pyrimethamine usage at my own hospital, Massachusetts General Hospital (MGH),

was the compounded suspension produced by our own compounding pharmacy," and then you cite Defense Exhibit 468, correct?

A. Yes, sir.

MR. MEIER: Mr. Tuttle, would you please put Defense Exhibit 468 on the screen.

And while he's doing that, I'll say that it has been admitted in evidence as part of Defense Exhibit 902.

Q. And you've seen this before, correct?

A. I believe so.

Q. So I don't have the time anymore to read all the paragraphs, but Mass General Hospital pharmacists compound pyrimethamine in advance of a specific patient's needs, correct?

A. That is my understanding.

Q. And although Daraprim comes in a tablet form, compounded pyrimethamine at MGH is an oral suspension, correct?

A. Yes, sir.

Q. And MGH-compounded Daraprim is only dispensed by the pharmacy with approval from an infectious disease specialist at MGH, correct?

A. That's correct.

Q. So noninfectious disease specialists, like you, can't approve the use of compounded pyrimethamine at MGH without approval, correct?

A. That's correct.

Q. And even at MGH, outpatients who need pyrimethamine are given Daraprim, correct?

A. That is my understanding.

MR. MEIER: You can take that down.

The last thing I'd like to show you, Mr. Tuttle, assuming I still have a minute left — I think I do — would you please put Defense Exhibit 456 on the screen.

Q. Do you know a Dr. Rajesh Gandhi at Mass General Hospital?

A. Yes. He's an infectious disease doctor at Mass General.

Q. Have you seen this email before?

A. I may have, but I don't specifically recall, but I may have.

(Continued on next page)

Q. Dr. Gandhi is writing to Dr. Hardy, among others, in April of 2019 and he says: The situation at MGH is as follows: We have been unable to access pyrimethamine through a noncommercial source, but that will no longer be the case as of September 2019. As a result, our patients will either need to use the commercial product, 400 to $900 per 25-milligram tablet, or we will be forced to switch to trimethoprim/sulfamethoxazole instead. Do you see that?

A. I think you may have misread. You said: We have been unable. It says we have been able to access pyrimethamine. Otherwise, I agree with that.

Q. I'm sorry. It does say that. In other words, it can get it through a noncommercial source, but if it tries to get it through commercial sources it has to pay a lot more?

A. That's correct.

MR. MEIER: Thank you, your Honor. I think I have a few minutes left for recross, if necessary.

REDIRECT EXAMINATION

BY MR. McDONNELL:

Q. Good morning, Dr. Jena.

A. Good morning.

Q. You were asked yesterday and today by counsel for plaintiffs about Dr. Hardy. Do you remember that?

A. Yes, sir.

Q. Have you reviewed Dr. Hardy's trial testimony in this case?

A. I have.
Q. Has that review of Dr. Hardy's trial testimony impacted your opinions in this case at all?
A. No, sir, it hasn't.
Q. You were asked a little bit about the direct versus indirect approach to market definition. Can you just please describe for the Court the differences between the indirect approach to understanding a relevant product market versus the direct approach.
A. Sure. If anything is unclear, let me know. A direct approach looks at evidence of the market price as it compares to a competitive price and that can be difficult to assess. The indirect approach starts with defining the relevant antitrust product market and then computing market shares in that product market.

So the handbook to which Mr. Meier referred, it starts with the assessment that although it is possible-- although courts primarily rely on an indirect approach, a direct-evidence approach can be useful, and I would absolutely agree with it. I think both sets of metrics are important to understand.

Q. In your experience as an economist which approach is more reliable to defining a relevant product market?
A. I think both are required because they can tell you different things perhaps. Certainly I think that an indirect

approach is useful. But I would want to consider both.

MR. MEIER: Your Honor, I object to this line of testimony. I would ask if I could voir dire the witness to see whether he has actually ever defined a market in any case.

THE COURT: You may voir dire.

MR. MEIER: I will just do it from here.

VOIR DIRE EXAMINATION

BY MR. MEIER:

Q. Dr. Jena, have you actually ever defined an antitrust product market in any of your academic work, in your consulting work, or in your work as a testifying expert in a case?

A. Yes, sir.

Q. What case was that?

A. Do I have a copy of my testimony list here?

Q. You didn't include it.

A. I don't know what I can speak about, but in the cholesterol market I defined the antitrust market for lipid-lowering drugs. I have defined the relevant antitrust market in setting up antiseizure or antiepileptic medications. I have defined the antitrust market for anticoagulants.

MR. MEIER: Your Honor, I withdraw my objection.

THE COURT: Thank you.

Q. Thank you, Dr. Jena. No further questions.

THE COURT: Any recross?

MR. MEIER: No, your Honor.

THE COURT: You may step down.

THE WITNESS: Thank you. I appreciate it.

(Witness excused)

MR. CASEY: Your Honor, the defendants have no more evidence, so we would rest.

THE COURT: Thank you.

I have commented before on how helpful the physical assembly of evidence has been to me to assist my review, both deposition binders and, where I had them, the witness affidavit binders with exhibits.

So I know that attorneys are present in the courtroom, but there are teams behind them. Not everybody gets to travel to New York. Not everybody gets to travel to the courthouse, particularly at a time of COVID. So please extend my gratitude to the teams.

Both sides here have had excellent assistance from those trying to display the evidence so that I could look at it with ease during the examination of the witnesses. Sadly, we had some equipment problems due to the courthouse equipment, not to counsel's equipment. But you soldiered on and overcame that and it really helped me understand the relevant evidence as counsel discussed it, so I want to give my thanks to those members of your teams as well.

I am going to single out the FTC for giving so many of its younger members of its team -- I think they were all FTC

lawyers. But maybe I'm wrong. Maybe some came from the New York AG's office.

Counsel, can you help me? Did some come from the AG's office.

MS. HOFFMANN: Your Honor, so far, all of the lawyers examining witnesses have been FTC lawyers, except me. There will be someone speaking tomorrow from the New York AG's office.

THE COURT: Thank you. I think it's noteworthy that so many opportunities were given to young lawyers to appear in court. I think that's a very important practice for counsel. The mentoring and training of young lawyers is critical to our profession.

Lastly, and I may think of more things to commend. But counsel have really cooperated so well with each other. You identified evidentiary and legal disputes for me. I gave you rulings and then you took those and applied those across the board and I think saved all of us an enormous amount of time and energy so we could focus on the core evidence. I want to thank counsel for cooperating so effectively with each other. I expect there were a few bumps in the road on that process, but somehow you soldiered on and managed to bring this evidentiary portion of the trial to a close.

There was a trial scheduled here with many more defendants, but there was a settlement on the eve of trial for

everyone except Mr. Shkreli.

Mr. Shkreli's trial team had to wear many hats that it probably had no idea it would have to wear. I want to acknowledge the effort during the holiday period that went into that.

Let's talk about summations. I think what would be most effective for me -- and I don't know what counsel's desires are, but I'll be happy to hear from you if you have a different idea -- is to start with the plaintiffs' summation, since they bear the burden, then move in to defense summations, and then have a rebuttal from the plaintiffs.

The plaintiffs, however, should anticipate everything that they can in their opening summation. The defendant has a fair opportunity to respond to it in their summation. There may be some points of emphasis or some surprise that occurs in the defense summation. So I do want to give the plaintiffs a chance for a rebuttal.

Mr. Meier, do you have an anticipation of how long plaintiffs' opening summation will be, roughly?

MR. MEIER: Your Honor, we have been trying to work through that. I think we are shooting very hard to try to make that an hour. But I am just concerned that once you get going, it might be a little bit longer. I think with the summation, both the initial and rebuttal, I think we will get that done in an hour and a half.

THE COURT: There are no time limits. I am just trying to do this for planning purposes.

MR. MEIER: Understood. I think that's our best estimate.

We anticipate having three people speak. They are some of the people you have met over the course of the trial, but it won't be me.

THE COURT: Thank you.

For defense counsel, do you have an estimate of your summation right now?

MR. CASEY: Your Honor, at this point I would estimate roughly around 90 minutes, perhaps a little bit longer than that. But that's my best estimate at this point, your Honor.

THE COURT: I don't know if you are going to use demonstratives during your summations. If you are, and are able to, I would love a set of them printed out.

I know as soon as I'm off the bench I'll think of other things that I should have mentioned, but that's it for now.

Mr. Meier, anything else?

MR. MEIER: No, your Honor. But we will absolutely bring copies for the Court and for the clerks, and we do intend to use demonstratives.

THE COURT: Mr. Casey.

MR. CASEY: Your Honor, just one point of

clarification.

I believe Mr. Meier said that they intended to have three lawyers speak. Ms. Hoffmann indicated there would be someone from the state speaking. I don't if they could clarify how they are going to divide that up or who is going to speak.

THE COURT: I'm happy for you to talk to them. I assume, because the states are the ones making a request for monetary relief, that the state should be speaking. And there is a request for injunctive relief and I have to make a decision on liability.

MR. CASEY: I'll speak to them.

THE COURT: Good.

MR. CASEY: Nothing further.

THE COURT: That's it, Mr. Casey? I wanted to make sure you had an opportunity for any question or comment. Nothing more?

MR. CASEY: Thank you, your Honor.

THE COURT: Good. Enjoy today and I'll see you tomorrow at 9:30.

(Adjourned to December 22, 2021 at 9:30 a.m.)

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DEFENDANT EXHIBITS